Attorney's Docket No.: 06275-124001 / D 1671-1P US

#22
DK
10/15/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Carin Widerstrom
Serial No. : 09/051,443
Filed : April 10, 1998
Title : DISPOSABLE INHALER

Art Unit : 3735
Examiner : Joseph F. Weiss, Jr.

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

(1) Real Party in Interest

The real party in interest is AstraZeneca AB.

(2) Related Appeals and Interferences

There are no related appeals or interferences known to Appellant.

(3) Status of Claims

Claims 1-5 and 7-12 stand finally rejected in the Office Action dated December 18, 2002 and are under appeal. Claim 6 has been cancelled.

(4) Status of Amendments

None of the claims have been amended subsequent to the final rejection of December 18, 2002.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

October 2, 2003
Date of Deposit

Jennifer Leveille
Signature

Jennifer Leveille
Typed or Printed Name of Person Signing Certificate

(5) Summary of Invention

The invention, as claimed in independent claims 1, 9 and 10, relates to a "single-use inhaler" for administering medicament by inhalation and methods of inhalation with such a device. Single-use inhalers provide a single use of medication, and are typically designed asdisposable devices that are thrown away after one use. An example of a prior art single-use inhaler is shown in Figs. 1 and 2 of the application, copied below. It is made of two parts 1 and 2 that together form an inhalation channel ending at a mouthpiece 5. It has a medicament containing recess 3 that is covered with tape 6 prior to use.

Fig. 1

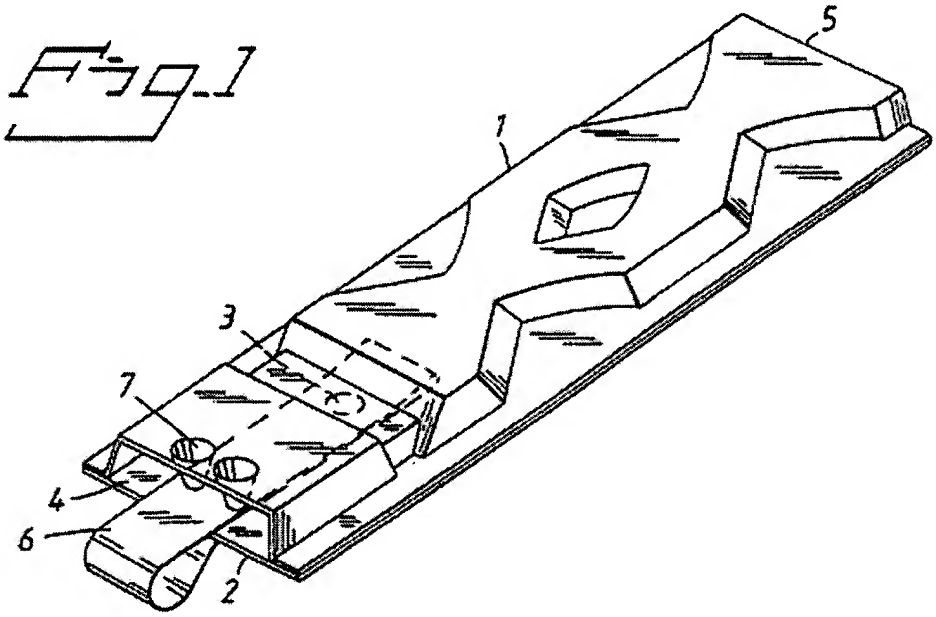
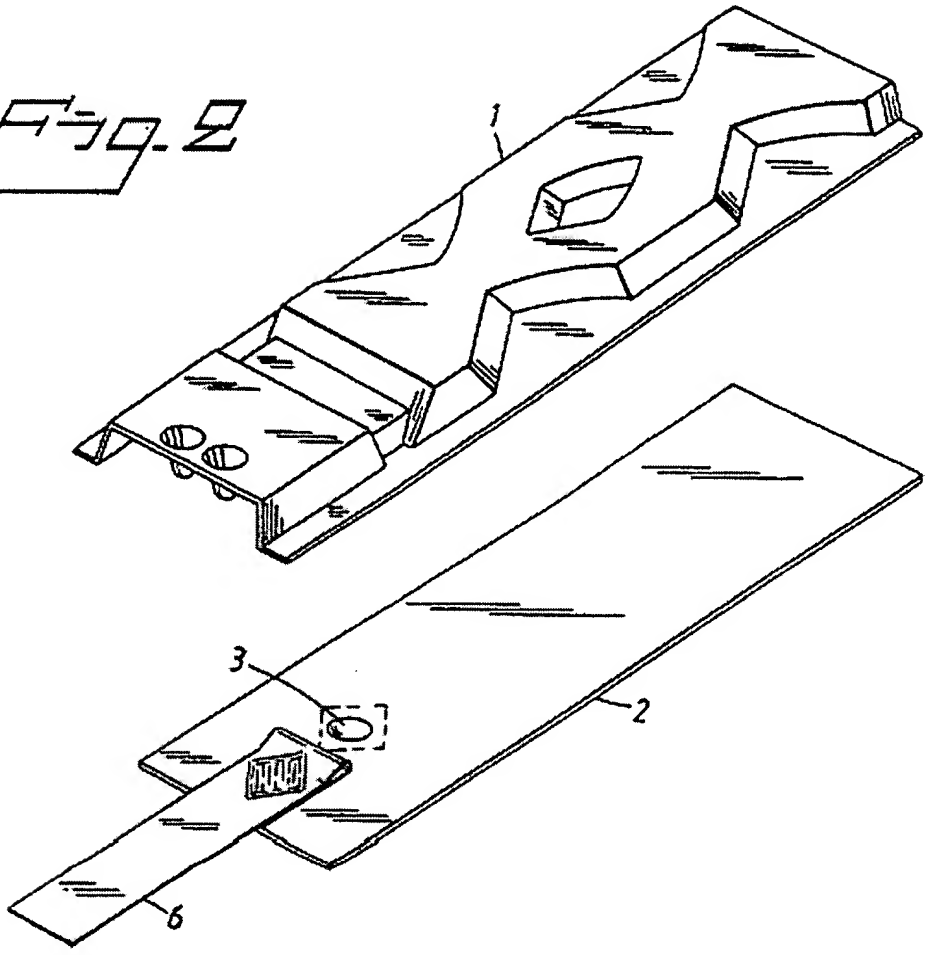


Fig. 2



Single-use inhalers are thus distinguished from multiple-dose inhalers, which are designed to be used multiple times.

Independent claim 1 is directed to a single-use inhaler that includes an inhalation channel through which the user inhales to entrain medicament in the channel. The inhaler also includes a first container and a subsidiary container each containing respective doses of medicament and a first release means and a subsidiary release means to release respective doses from the respective containers into the inhalation channel. The subsidiary dose is less than the first dose, and the release means for it can be activated to release the subsidiary dose at the same time as the first dose.

An example of such a device is shown in the application in Figs. 3 and 4 copied below. The device includes two medicament containing depressions 18, 20 and respective covering tapes 22, 24.

Fig. 3

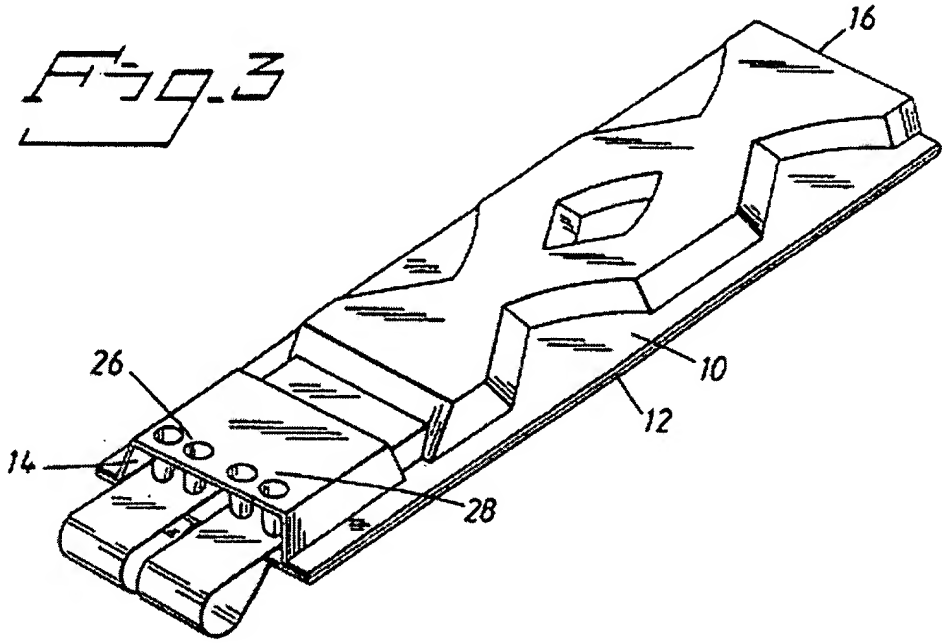
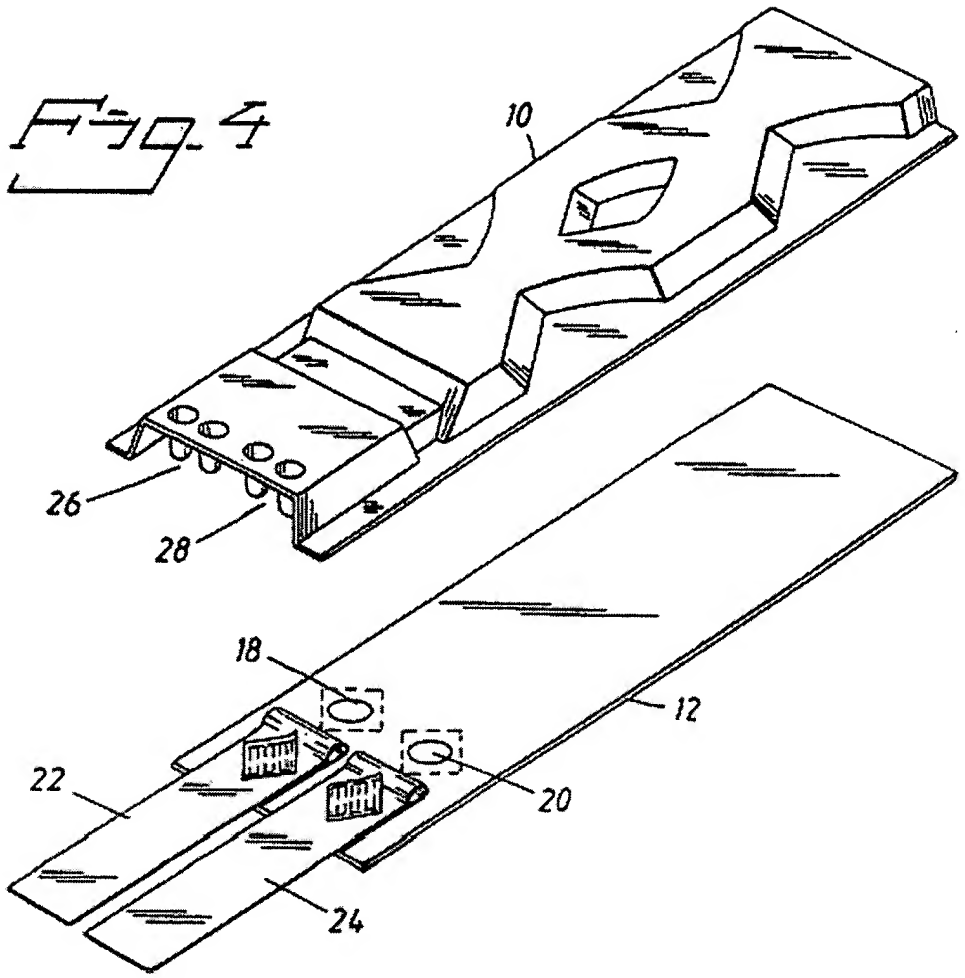


Fig. 4



Independent claim 9 is similar in scope to claim 1, though it is drafted as a "method for providing a variable dose in a single use inhaler" and recites providing the first and subsidiary containers and first and subsidiary release means, and arranging for said first release means to be independently operable of said subsidiary release means such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time such that a variable dose is provided.

Independent claim 10 is directed to a method of providing a variable quantity of substance in a channel of an administration device that includes the steps of opening a first container containing a dose of the substance and dispensing the substance in the channel, selectively opening a subsidiary container containing a subsidiary dose of the substance (smaller

than the first dose) according to the total quantity of substance required, and dispensing the substance in the channel.

(6) Issues

Whether independent claim 1 and dependent claims 2-5 and 7-8 are obvious under 35 USC 103(a) in view of Goettenauer (DE 4400084A1) in view of Gonda U.S. Patent No. 5,743,250 ("Gonda '250").

Whether independent claim 9 is obvious under 35 USC 103(a) in view of Goettenauer U.S. Patent No. 5,881,719 in view of Gonda '250.

Whether independent claim 10 and dependent claims 11-12 are obvious under 35 USC 103(a) in view of Goettenauer '719 in view of Gonda '250.

Whether independent claim 1 and dependent claims 2-5 and 7-8 are obvious in view of claims 1-19 of U.S. Patent No. 5,533,505 in view of Gonda '250 and therefore subject to an obviousness-type double patenting rejection.

(7) Grouping of Claims

Independent claim 1 and dependent claims 2-5 and 7-8 stand or fall together.

Independent claim 9 stands alone.

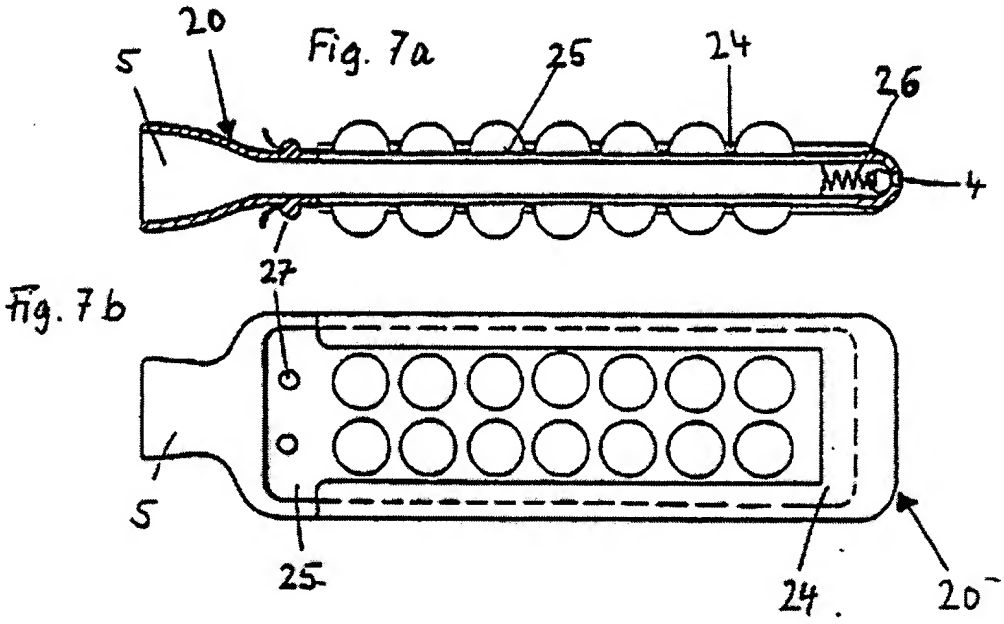
Independent claim 10 and dependent claims 11-12 stand or fall together.

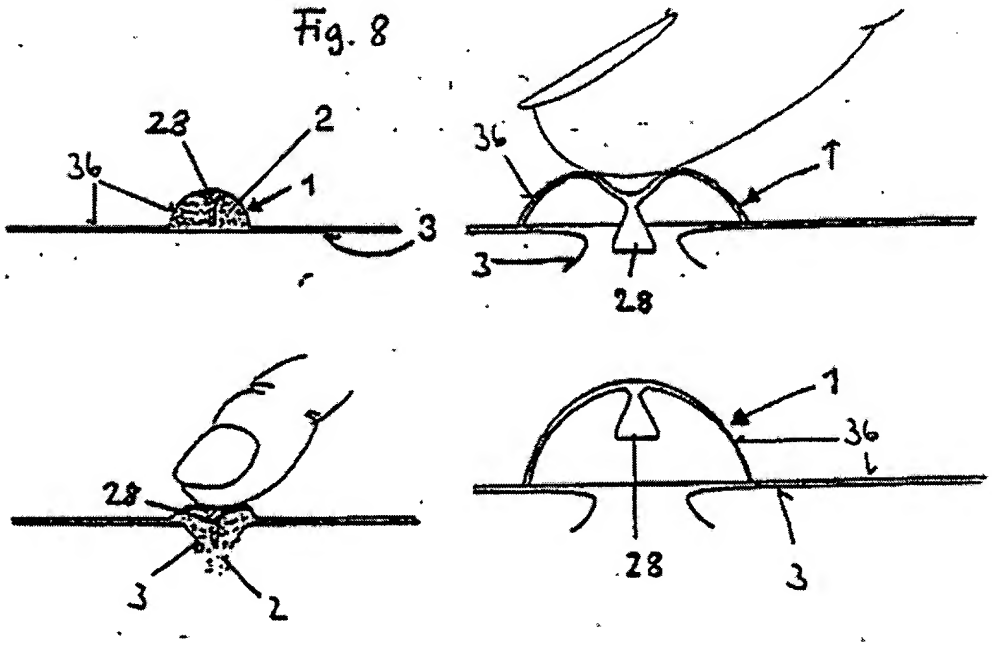
(8) Argument

A. Independent Claim 1 Is not Obvious in view of Goettenauer '084 in view of Gonda '250

Independent claim 1 stands rejected as rendered obvious under 35 USC 103(a) in view of Goettenauer DE 44 00 084 ("Goettenauer '084") and Gonda U.S. Patent No. 5,743,250.

Goettenauer '084, Figs. 7-8 of which are copied below, shows an inhaler with a large number of openable containers of medicament.





Goettenauer '084 thus describes a multiple-dose inhaler, not a single-dose inhaler. Goettenauer '084 also nowhere discloses, teaches or suggests a subsidiary dose that is less than the primary dose, as is required by independent claim 1

Gonda '250 describes a device, shown in Fig. 4 below, for delivering insulin by inhalation. The device includes liquid medicine 3 that is released to an inhalation channel by operating piston 24 under the control of a microprocessor in response to sensing inhalation.

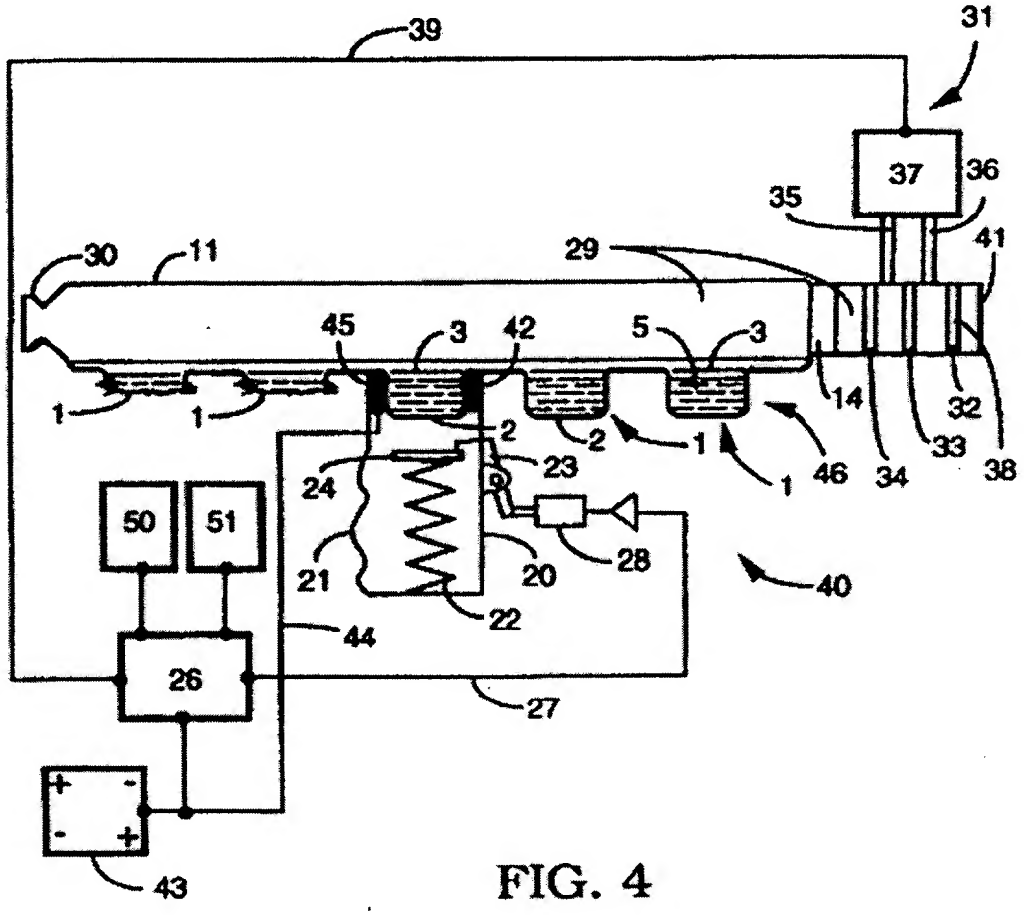


FIG. 4

The delivery of medicine can occur over a number of inhalations, and the piston can deliver less than the contents of a container in one inhalation, and, if necessary, advance to a new container between inhalations.

In the office action it is asserted with respect to Gonda '250:

> However, Gonda disclose such [a subsidiary dose that is less than the primary dose] (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these differences

being predetermined when the blisters are filled, note the abstract for the use of a dry powder).

The abstract describes enhancing absorption by instructing the patient to inhale maximally and thereafter exhale maximally. The abstract also describes an electronic sensor that measures air flow and volume when the patient is inhaling in order to control the precise point in time of drug release. The sensor can also assist the patient in the inhale-exhale maneuver, which is later called "coaching." The abstract says nothing about repeated deliveries of medicament.

Col. 42 describes "indices" that are included with the drug containers. The indices may be electronic (col. 42, lines 6-7) and provide information to the patient (col. 42, line 14). The indices "can be designed for any desired purpose but in general provide[] specific information relating to the day an/or time which the drug within a container should be administered" (col. 42, lines 14-17). The indices can also provide information on the "amount of insulin dispensed from each container which might be particularly useful if the containers included different amounts of insulin." (col. 42, lines 26-28). The indices "could have new information [e.g., time of delivery] recorded onto them which information could be placed there by the drug dispensing device." (col. 42, lines 29-35).

While the passage at col. 42 indicates that there could be different amounts of medicament in different containers, there is no indication that the different containers in the same strip should have different amounts, or that a patient should take drugs from two separate containers to get a variable dose.

Gonda '250 also describes setting the piston of the drug release device to release all or a percentage of the contents of a container at col. 23, lines 26-30, and moving from one container to another in a dosing event involving several inhalations at col. 31, lines 47-52. There still, however, is no teaching or suggestion of taking drugs from containers with different doses in order to get a variable dose, as required by claim 1.

The cited references, taken alone or in combination, do not disclose or suggest a single use inhaler with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsidiary dose with the primary dose to provide a variable dose as required by claim 1, and claim 1 is patentable under 35 USC 103(a).

Claims 2-5 and 7-8 depend on claim 1 and are allowable with it.

B. Independent Claim 9 Is not Obvious in view of Goettenauer '719 in view of Gonda '250

In the rejection of claim 9, Goettenauer U.S. Patent No. 5,881,719 ("Goettenauer") is cited as the primary reference for disclosure of a device with first and second doses and release means, and Gonda '250 is combined with the primary reference in the same manner as in the rejection against claim 1 for disclosure of "predetermined fractions of doses of one blister relative to another," citing the abstract and col. 42.

Goettenauer '719 describes, in Fig. 5 copied below, a device with four containers and four pressing-out levers 9.

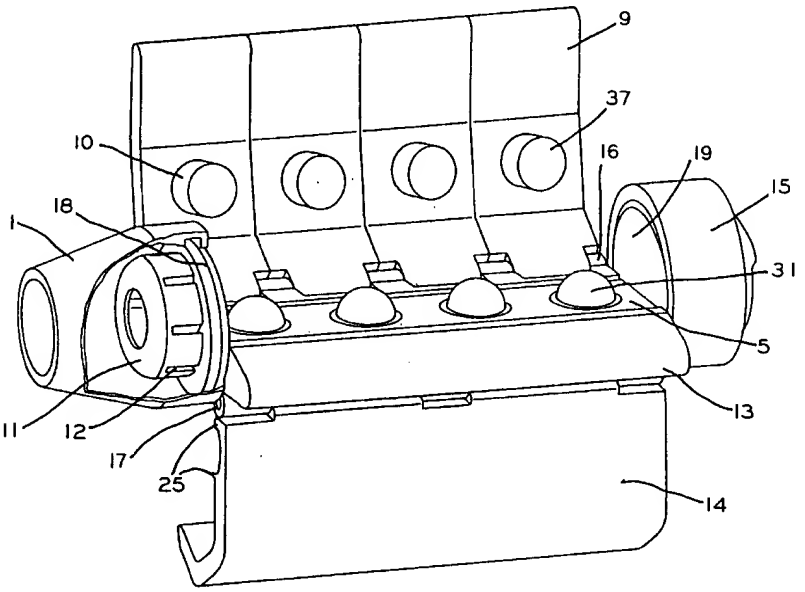


FIG. 5

Goettenauer '719 thus also appears to describe a multiple-dose inhaler, not a single-dose inhaler. Goettenauer '044 also nowhere discloses, teaches or suggests a subsidiary dose that is less than a primary dose, as is required by independent claim 9.

In this rejection, Gonda '250, the secondary reference, suffers from the same deficiencies already described above with respect to the rejection of claim 1. There is no teaching or suggestion in Gonda '250 of providing at least one subsidiary container that contains a subsidiary

dose of medicament that is a predetermined fraction of the first dose, as required by claim 9. Also, while Gonda '250 describes setting the piston of the drug release device to release all or a percentage of the contents of a container at col. 23, lines 26-30, and moving from one container to another in a dosing event involving several inhalations at col. 31, lines 47-52, there still, however, is no teaching or suggestion of taking drugs from containers with different doses in order to get a variable dose, as required by claim 9.

The cited references, taken alone or in combination, do not disclose or suggest a single use inhaler with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsidiary dose with the primary dose to provide a variable dose. Claims 9 thus is patentable under 35 USC 103(a).

C. Independent Claim 10 Is not Obvious in view of Goettenauer '719 in view of Gonda '250

The rejection of claim 10 on Goettenauer '719 in view of Gonda '250 suffers for the same reasons as the rejection of claim 9.

Claim 10 recites "selectively opening a subsidiary container containing a subsidiary dose of said substance according to the total quantity of substance required and dispensing said substance in said channel wherein said subsidiary container contains an amount of said substance which is a predetermined fraction of the amount of the substance contained in the [first] container"

Goettenauer '719 nowhere describes selectively opening a subsidiary container with a smaller dose, or doing so to obtain a variable does.

Also, while Gonda '250 describes setting the piston of the drug release device to release all or a percentage of the contents of a container at col. 23, lines 26-30, and moving from one container to another in a dosing event involving several inhalations at col. 31, lines 47-52, there still, however, is no teaching or suggestion of selectively opening a subsidiary container with a smaller dose, as required by claim 10.

The cited references, taken alone or in combination, do not disclose or suggest a method of providing a variable does that involves opening a first container with a first dose, and a

selectively opening a subsidiary container with a subsidiary dose that is less than the first dose to provide a variable dose. Claim 10 thus is patentable under 35 USC 103(a).

Claims 11 and 12 depend on claim 10 and are allowable with it.

The remaining claims depend on the independent claims and are allowable with them.

D. Claims 1-5 and 7-8 Are not Obvious in view of Claims 1-19 of U.S. Patent No. 5,533,505 in view of Gonda

Claims 1-5 and 7-8 have also been rejected for obviousness type double patenting on the basis of Kallstrand U.S. Patent No. 5,533,505 considered in view of Gonda U.S. Patent No. 5,743,250.

Kallstrand '505 only shows a device with a single compartment that is similar to the prior art inhaler described at Figs. 1 and 2 of the present application. Claims 1-19 are set forth below.

1. A disposable breath-actuated inhaler for delivering a dose of a finely divided powder to a patient comprising

a housing defining a chamber, said chamber having an air inlet,

an air outlet in fluid communication with the air inlet, and an air flow path extending between said inlet and said outlet

a compartment, containing a dose of finely divided powder, located in a region of said chamber intermediate said inlet and said outlet, said compartment defining a volume to hold the dose and having an opening which exposes a surface of said dose to said air flow path, said compartment including a through-hole positioned beneath the finely divided powder, said through hole selectively opened to ambient air to allow ambient air to enter the compartment,

a removable cover disposed sealingly over said opening in said compartment and confining the dose of finely divided powder within the compartment prior to delivery, and

a constriction means in said air flow path adjacent the powder compartment positioned to induce sufficient turbulence in an air stream produced upon removal of said removable cover and subsequent inhalation to lift the powder out from the compartment and mix the powder into the air stream for delivery through the air outlet.

2. An inhaler according to claim 1 wherein said powder compartment includes a

plurality of through-holes.

3. An inhaler according to claim 1, wherein said housing comprises an upper half and a substantially flat lower half having an indentation forming the powder compartment, said two halves being sealingly joined along their longitudinal sides.

4. An inhaler according to claim 3, wherein the upper part is moulded from a thin plastic sheet.

5. An inhaler according to claim 3 or 4, wherein said constriction means is formed as a depression in said upper part which depression is oriented transversely relative to the longitudinal extent of the tubular housing and located above the powder compartment.

6. An inhaler according to claim 3, wherein the lower half comprises a laminate including an aluminum foil layer and a plastic layer.

7. An inhaler according to claim 1, wherein the cover comprises a thin foil in the shape of a tape having a free end extending out through the air inlet, said tape being attached around the edges of the powder compartment by relatively weak welds.

8. An inhaler according to claim 7, wherein an inner end of the tape, spaced from said free end, is attached to an inner surface of the lower half between the air inlet and the powder compartment, and the tape extends away from the air inlet past the powder compartment, and then bends backwards so as to extend toward and out through the air inlet.

9. An inhaler according to claim 8, wherein the weak welds form a point facing downstream in the airflow path in order to facilitate the initiation of the tearing action along the welds when the tape is pulled out of the housing to expose the powder.

10. An inhaler according to claim 8 wherein said free end of said tape is attached to an outer surface of said lower part and positioned to seal said through-hole.

11. An inhaler according to claim 1 wherein said housing further comprises a projection extending downwardly from the upper half between the powder compartment and the air inlet for holding the tape against the lower half of the housing in order to prevent the tape from obstructing the air flow path.

12. An inhaler according to claim 1 wherein said housing further comprises deaggregation means located in the air flow path between the powder

compartment and the air outlet.

13. An inhaler according to claim 11, wherein said deaggregation means comprise a plurality of planar surfaces defining said air flow path, each surface being oriented at an angle of from about 20° - 50° relative to the longitudinal direction of the tubular housing, said surfaces being disposed generally perpendicularly to a plane through the longitudinal axis of the tubular housing, a projection of the planar surfaces onto a cross-section of the housing substantially covering said cross-section.

14. An inhaler according to claim 13 wherein said angle is from about 25°-35°.

15. An inhaler according to claim 1 wherein said compartment includes two through-holes.

The claims in this pending application require, in addition to the first container, a further container with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsidiary dose with the primary dose to provide a variable dose. This is nowhere suggested by the claims of the '505 patent. This feature also is nowhere disclosed or suggested in Gonda '250, as noted above, and the rejection should be withdrawn. This is more than the duplication of a known part for a known purpose, because it permits the user to make a decision and select a larger dose.

The brief fee of $320 is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: Oct 2, 2003

William E. Booth
Reg. No. 28,933

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

Appendix of Claims

1. A single use inhaler for administering medicament by inhalation, the inhaler comprising:

an inhalation channel through which a user may inhale;

a first container containing a first dose of medicament; and

a first release means for releasing said first dose into the said inhalation channel; wherein the inhaler further comprises:

at least one subsidiary container containing a subsidiary dose of medicament;

at least one respective subsidiary release means for releasing said subsidiary dose into said inhalation channel; wherein

said first release means is independently operable of said at least one subsidiary release means such that one or more of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose is provided and the subsidiary dose of said at least one said subsidiary container is a predetermined fraction of said first dose that is less than said first dose.

2. An inhaler according to claim 1 wherein said container and said at least one subsidiary container are integral parts of the inhaler.

3. An inhaler according to claim 2 wherein said container and said at least one subsidiary container comprise depressions in at least one wall of said inhalation channel and said release means and said subsidiary release means respectively comprise films sealing said depressions.

4. An inhaler according to claim 3 wherein said first release means and said subsidiary release means comprise one or more elongate members attached to or integral with said films and with respective free ends which may be pulled by a user in order to remove the films from their respective depressions, thereby releasing the medicament contained in the respective depressions.

5. An inhaler according to claim 1, wherein said medicament is in a powdered form.

7. An inhaler according to claim 1 wherein the inhaler comprises at least two subsidiary containers containing further subsidiary doses and the further subsidiary doses of each of said at least two subsidiary containers is a predetermined fraction of said first dose that is less than said first dose.

8. An inhaler according to claim 7 wherein said subsidiary doses include different predetermined fractions of said first dose.

9. A method of providing a variable dose in a single use inhaler having an inhalation channel through which a user may inhale, a first container containing a first dose of medicament and a first release means for releasing said first dose into said inhalation channel, said method comprising;

providing at least one subsidiary container in said single use container [sic "dispenser"] containing a subsidiary dose of medicament whereby the subsidiary dose of said at least one said subsidiary container is a predetermined fraction of said first dose that is less than said first dose;

providing at least one respective subsidiary release means for releasing said subsidiary dose of medicament into said inhalation channel; and

arranging for said first release means to be independently operable of said subsidiary release means such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose is provided.

10. A method of providing a variable quantity of substance in a channel of an administration device, comprising the steps of;

opening a first container containing a dose of said substance and dispensing said substance in said channel;

selectively opening a subsidiary container containing a subsidiary dose of said substance according to the total quantity of substance required and dispensing said substance in said channel wherein said subsidiary container contains an amount of said substance which is a predetermined fraction of the amount of the substance contained in the container.

11. The method of claim 10 wherein said administration device administers a medicament and said substance is said medicament.

12. The method of claim 11 wherein said administration device is an inhalation device.

PTO 2000-2494

Germany
4,400,084

DEVICE FOR ADMINISTERING MEDICATIONS IN SOLID FINELY DISPERSED FORM IN AN AIR FLOW

[Vorrichtung zum Verabreichen von Medikamenten in fester in einem Luftstrom fein verteilter Form]

W. Goettenauer et al.

UNITED STATES PATENT AND TRADEMARK OFFICE
Washington, D.C. May 2000

Translated by: Schreiber Translations, Inc.

Country	:	Germany
Document No.	:	4,400,084
Document Type	:	Patent application
Language	:	German
Inventor	:	W. Goettenauer, Andre Narodylo, Joachim Goede, and Werner Friedmann
Applicant	:	Asta Medica AG
IPC	:	A61M 15/00
Application Date	:	04 January 1994
Publication Date	:	06 July 1995
Foreign Language Title	:	Vorrichtung zum Verabreichen von Medikamenten in fester in einem Luftstrom fein verteilter Form
English Title	:	DEVICE FOR ADMINISTERING MEDICATIONS IN FIXED FINELY DISPERSED FORM IN AN AIR FLOW

/1[1]

A device for administering medications to patients in solid finely dispersed form in an air flow is described, which has an outwardly sealed housing (33) that forms an elongated inner chamber with a mouthpiece-shaped air outlet (5) arranged on a narrow side and an air inlet opening (4) arranged on the opposite side, wherein the housing (33) has, on its (their) main surface area(s), small cavities (1) on a container foil which are open toward the inner chamber for receiving the medication, which are closed off as a package via a thin cover foil, wherein the cavities (1) are bulged outwardly in dome shape and the container foil in the area of the cavities (1) has such a stiffness and/or elasticity that, when a pressure is exerted on the domes (1) from outside, the cover foil ruptures and a release of the medication into the inner chamber is made possible. /2

Description

The invention concerns a device for administering medications in solid finely dispersed form to a patient via inhalation. The device according to the invention can also be called a power inhaler.

Powder inhalers are nowadays used in great number and in many embodiments in inhaling therapy and substitute the

---

[1] Numbers in the margin indicate pagination in the foreign text.

suspension inhalers which were commonly used until now, wherein the aerosol was produced by means of a halogenated hydrocarbon as propellant and whose use was no longer desired due to issues related to the protection of the environment. All the previously known powder inhalers used a technically relatively complicated configured device with which powder portions (doses) were sent to the lungs of the patient via inhalation. The powder portions are dosed either directly into the inhaler (as in, for example, German patent publication 4,211,475, European patent publications 0,407,028, 0,387,222, 0,237,507, and 0,069,715) or the medication is introduced in already premeasured form into the inhaler and released via corresponding means. Powder inhalers which use packaged powder portions are described in European patent publication 0,406,893 and German patent publication 2,704,574.

Another possibility of premeasuring medications is the packaging of corresponding portions in so-called "blister packages," which are generally known for packaging tablets which provide the possibility of removing them individually in a hygienic manner. European patent publication 0,211,595, British patent publications 2,129,691 and 2,142,246 disclose powder inhalers which release the medication contained in blister packages in solid finely dispersed form. In the powder inhalers disclosed in European patent publication 0,211,595 and British patent publication 2,129,691, a disc-shaped blister package is

introduced, which releases the powder portions for use of the inhaler via a plunger, and the blister disc, when completely emptied, is replaced by a new one. British patent publication 2,142,246 concerns an inhaler in which a blister package made up by a single chamber is introduced and which is opened via a type of filler pin for use.

The powder inhalers used until now have the disadvantage that they are uncomfortable to use, that is, the device volume is relatively large with respect to the apportioned dose quantity. Carrying a known powder inhaler can be quite uncomfortable for the patient, depending on the volume and quantity of parts per device. There is also the danger with the different and often complicated operation principles that the devices are very difficult or impossible to utilize in case of an emergency (for example, during an acute asthma attack) or due to insufficient technical knowledge by the patient. Furthermore, the powder inhalers described until now consist generally of several parts of different materials; an environmentally friendly disposal is therefore not necessarily possible.

The object of this invention is to prevent the above-mentioned disadvantages and to make available to the patient an inexpensive inhaler that is easy to use.

The object is attained via a device for administering medications in solid finely distributed form in an air flow to

patients, which has a housing sealed toward the outside which forms an elongated inner chamber with a mouthpiece-shaped air outlet at a narrow side and an air inlet opening arranged on the opposite side, characterized in that the housing(s) has (have) small cavities for receiving the medication which are open to the inner chamber on its (their) main surface area(s) and which are closed off as a package via a thin cover foil, wherein the cavities are bulged outwardly in dome shape and the container foil has a stiffness and/or elasticity in the area of the cavities so that, when a pressure is exerted on the domes from outside, the cover foil ruptures and a release of the medication into the inner chamber is made possible.

When the user needs a dose of medication, he pushes with one finger on one of the outwardly bulging domes of the package of the device according to the invention which contain the medication in solid finely dispersed form. The pressure on the dome effects that the thin cover foil ruptures and the medication either remains in the cavity via adhesion forces, or falls directly into the inner chamber of the housing. The patient produces an underpressure by suction on the mouthpiece-shaped outlet, which has the effect that the medication is conveyed almost completely out of the inner chamber and air penetrates through the air inlet opening into the inner chamber. The air flow exits then and takes with it the medication via the

mouthpiece-shaped outlet from the device and is inhaled by the user, whereby the medication arrives in the lungs of the patient. Since the air flow also produces a partial underpressure (injection effect) in the inner chamber of the housing when flowing in through the open cavity, the medication is largely extracted without leaving behind a residue.

Packages that consist of a container foil with small filled recesses, which can also be called cavities, and a cover foil that closes off the recesses, are generally called blister packages. In this invention, the term "blister package" is to be understood in the amplest possible sense for such packages, independently from the type of container foil or its production method. The cover foil can be connected to the container foil in different ways, for example, usually by welding or gluing.

The material of the container foil is preferably a deep-drawn polymer such as polypropylene, polyethylene, polyvinylchloride, polystyrol, or a deep-drawn metal such as aluminum laminated with a polymer. Suitable are also other deep-drawn materials otherwise used for blister packages. Molded parts with cavities produced in a deep-drawing process have an even wall thickness of the container foil in the areas of the cavities as well as also in the other areas. As material for the container foil, but for example also an injection molded material or another cast material or a material processed via blister

molding, for example, an elastomer material, can be used and the molded part can be produced with the cavities in correspondence to an injection molding process or another casting process or via blister molding. The wall thickness of the container foil can be varied in different areas according to need.

The cover foil is preferably made of metal, for example, aluminum or aluminum alloy, laminated with a polymer. Also other materials can be used, among others the usual and known materials used for blister packages. /3

The medication is placed in the cavities in solid form, which makes possible a dispersion of the medication in the air flow in finely dispersed form. Suitable solid forms are, for example, powder, granulate, pellets, or grain agglomerates.

In the area of the cavities or domes, the container foil has a wall thickness that allows the dome to be pushed outward, for example, by means of a finger, and the cover foil ruptures. For facilitating the pushing in of the dome, a pressure line can be provided on the outside of the housing.

To prevent that the medication is pressed together when the pressure is exerted on the dome and can therefore not be sufficiently dispersed in the air flow, it is advantageous to configure the domes or cavities in such a way that the cavities closed off by the foil can be opened without or with very little mechanic stress on the medication. In an embodiment of the

device, therefore, an inwardly directed filler pin or an inwardly directed spacer is present on the inside of the container foil in the cavities. When pressure is exerted on the dome, the filler pin or spacer pushes through the cover foil and the cover foil ruptures. Another embodiment possibility for a dome or cavity which can be open without or with very little mechanical stress on the medication consists in surrounding the cavity by an at least partially surrounding ring bulge, which is molded in the container foil.

Due to reasons of an optimum air guide in the inner chamber of the housing it is advantageous to tear off or separate the cover foil in a defined manner. It is desired that the part of the cover foil which originally had closed off the cavity projects into the inner chamber after opening as a kind of flap attached only at one point, wherein the flap can be directed parallel to the air flow. This is attained, for example, in that the dome is only partially surrounded by a ring bulge, whereby the cover foil is separated in the area of the bulge and remains attached to the rest of the cover foil in the area where the bulge is interrupted. A similar effect is also obtained, for example, in that the cover foil is provided with desired rupture areas. A defined rupturing of the cover foil is also promoted by the asymmetric configuration of the domes, for example, in a one-sided beveled form. To reinforce the defined directed tearing of

the cover foil, the different embodiments of the domes or their surrounding areas can also be intercombined.

In an embodiment of the invention, a blister package filled with medication is configured in the form of a winding which, after folding, straightening, and joining makes up the inhaler with a mouthpiece-shaped air outlet and a rear wall with air inlet opening. The sealed connection of the straightened winding for forming a preferably square-shaped or tube-shaped housing is carried out, for example, via welding, gluing, or via plug-in and locking connections; in this way, the winding can have additional latches for facilitating the connection to a housing. The cross section of a straightened and joined winding can, for example, be rectangular (square or quadratic), triangular, or circular. The individual cavities or domes can be arranged on one or several main surfaces of the housing.

In another embodiment, one or several blister packages build in the form of simple cutouts, after folding and straightening, form a preferably square-shaped hollow body, which is open toward the opposite-lying narrow side. On it are installed a front attachment part with mouthpiece-shaped air outlet and a rear attachment part with a rear wall having the air inlet opening and attached via suitable means to the hollow body. The attachment can be carried out, for example, in that the front attachment

part is connected to a rear wall and the hollow body is clamped between both attachment parts.

In another embodiment of the invention, the housing is configured by a structure which is open at one of its (their) surface(s) and an air inlet opening, in that one or several strips of a blister package are introduced, so that all the open main surfaces are sealed to the outside. The insertion of the blister strips can take place, for example, via insertion into corresponding recesses or the structure can be configured to be foldable and the strips are accommodated therein.

The air inlet opening can be, for example, a simple hole or can be provided with a flap produced by punching. To exclude erroneous functions or erroneous operations as much as possible, the inlet opening is preferably provided with a check valve, which opens when there is a low pressure in the inner chamber of the housing and which is closed when there is a normal pressure or an overpressure in the housing inner chamber. A suitable check valve is a diaphragm valve wherein a membrane is arranged on the inner side of the housing, which covers the inlet opening and comes to lie on the face area when there is an overpressure in the housing and which closes off the inlet opening. Also spring-loaded ball valves and other check valves can be used for closing off the air inlet opening.

The device can be provided with an additional separate hollow mouthpiece, which can be inserted on the mouthpiece-shaped air outlet. This mouthpiece, on the one hand, facilitates the inhalation of air during the inhaling procedure, and on the other hand, it can be exchangeable due to hygienic reasons.

It is advantageous to provide the mouthpiece-shaped outlet on the inside with components that improve the dispersion of the medication in the air flow, for example, by reinforcing the turbulence of the air flow.

In an embodiment of the invention, the device has additionally a protective sleeve which partially surrounds the housing. It encases, for example, the lower side of the housing and should prevent that the user inadvertently pushes one or several domes also on the lower side when pressing on a dome on the upper side of the housing.

To better stabilize the housing of the inhaler made up by a blister package, in particular during the force effect on the outwardly projecting domes, reinforcements can be arranged inside and outside of the housing. The reinforcements can be differently configured, for example, as bars running between the housing walls in longitudinal direction inside the device, which can effect simultaneously a partition of the air channel. /4

The container foil of the blister packages can also be provided with a foil film on its upper side. The same can be

applied directly on the container foil or, for example, in the embodiment, wherein the housing is formed by a structure open to the main surface(s), which closed off these openings. In this way is also obtained a housing that is sealed to the outside even then when the strips are not exactly accommodated.

The separate mouthpiece as well as the front and rear attachment are preferably made of sterilizable plastic such as thermoplasts processable via injection molding or via pressure molding or blister forming, for example, polyacrylates, polymethylacrylates, polycarbonates, polyolefines, or polyurethanes.

The entire device is preferably made of ecologically sound materials, which make possible an environmentally friendly disposal.

The advantages of the invention lie, above all, in the easy handling and the simple operation. The ratio of device volume to medication doses can be configured advantageously since technically complicated mechanisms for opening the blister packages are not necessary. The patient also knows about the opening of blister packages from other cases (pushing of tablets out of blister strips) and a safe operation of the device is therefore always ensured.

The invention will be further described with reference to the embodiments represented in the following figures.

Fig. 1 shows a perspective view of a device produced with a winding of a blister package in their simplest embodiment;

Fig. 2 shows the winding of the blister packages for the device of Fig. 1;

Fig. 2a is a section of a single cavity or dome of Fig. 2 along line A-B;

Figs. 3a and 3b show the housing of the device in cross section, wherein the straightened winding is held together by locking connections;

Figs. 4a and 4b show a perspective view of the inhaler made by straightening the windings of blister packages with two different housing cross sections;

Figs. 5 and 5a show a longitudinal section and a cross section of a straightened winding with additional protective sleeve, inserted mouthpiece, attachments as dispersion aid, and reinforcements in the inside of the housing;

Figs. 6a-d show an embodiment of the device made of two simple windings of a blister package and a front and rear insertion part;

Fig. 7 shows an embodiment of the device of a structure with two joined blister strips;

Fig. 8 shows a section through the schematically enlarged individual cavities or domes of a blister package with an inwardly directed filler pin or an inwardly directed spacer and

how the same push through the cover foil under the exertion of pressure;

Fig. 9 shows an enlarged representation of a cavity or dome with surrounding ring bulge; and

Fig. 10 shows a plan view of an embodiment of Fig. 9 with not completely surrounding ring bulge.

In Fig. 1 is shown a device produced with one single-piece winding of a blister package, which was formed by folding, straightening, and form-tight connecting the winding 34.

The housing 33 has an elongated inner chamber shaped as a right parallelepiped with domes which are enclosed in so-called blister packages on two opposite-lying main surfaces, as well as a rear wall 13 with an air inlet opening 4 arranged on the narrow side of the right parallelepiped having a flap and an opposite-lying mouthpiece-shaped outlet 5. The joining of the housing 33 is attained in that the edges of the winding 34 and eventually available latches 7 are glued together, welded, or otherwise connected. For use, the patient pushes in a dome 1 filled with the medication 2, separates in this way the cover foil 3 provided on the inside of the housing 33 to cover the cavity, 1 and the content of the cavity 1 is transferred into the housing inner chamber. By suction of the air through the housing inner chamber via the mouthpiece-shaped air outlet 5 results the administration of the medication 2 in the form of an air/solid mixture.

housing 33 whose inner chamber has a quadratic cross section and wherein all four of its sides have blister packages (Fig. 4a), and a housing 33 in tube shape is provided with domes 1 around the entire jacket surface (Fig. 4b).

The rear wall 13 of the housing 33 has an air inlet opening 4. On the opposite-lying hosing end is configured the mouthpiece-shaped air outlet 5. The air inlet valve 4 can be closed off via a not shown inlet valve to prevent an undesired escape of the medication 2 introduced in the housing inner chamber of a cavity 1 by inadvertent erroneous use of the inhaler. The inlet valve blocks when there is a normal pressure or an overpressure in the inside of the housing and opens, instead, when there is an underpressure which has been produced by the suction of air via the mouthpiece-shaped outlet 5. /5

Fig. 5 shows an embodiment wherein a housing 33 of a straightened and joined winding 34 is partially surrounded by a protective sleeve 11. The protective sleeve 11 covers the blister package on the bottom side of the housing 33 and prevents an inadvertent pushing in of the domes 1 on the bottom side. The surface of the sleeve 11 has cavities 32 which correspond in size to the domes 1 for receiving the domes 1. On the face area or narrow side of the sleeve 11 is provided an opening 12 which is aligned with the air inlet opening 4 to make possible the penetration of air into the housing 33. The air inlet opening 4

front attachment part 35 has the mouthpiece-shaped air outlet 5 and a rectangular-shaped cross section at the end facing away from the outlet end so that the rectangular-shaped hollow body 18 can grip into the front attachment part 35. Elements 22 of a locking device are also located on both side walls at the end facing away from the outlet of the front attachment part. The rear attachment part 19 has a hollow right parallelepiped with a face area 13 facing the hollow right parallelepiped and two side walls 21 extended in the direction of the hollow body 18. The face area 13 is surrounded by a groove 37 into which the hollow body 18 can grip. The air inlet opening 4 (not shown) is also located in the face area 13. The side walls 21 reach over the entire length of the hollow body 18 and are provided at their ends with elements 23 of a locking connection.

As shown clearly in Fig. 6c, the hollow body 18 shaped as a right parallelepiped is inserted into the rear attachment part 19 until it is surrounded by both extended walls 21 and the face area 13, the front attachment part 35 is inserted and both attachment parts 35 and 19 are interconnected via the elements 22 and 23 of the locking connection. In Fig. 6d it can be seen that the hollow body 18 made of two simple windings 17 is clamped between the attachment parts 35 and 19. In this way, the entire housing 33 is sealed to the outside. The face area 13 of the

together with the inserted blister strip 25, a housing 33 sealed to the outside.

To make easier the rupturing of the cover foil 3 over the cavities 1 filled with medication in the blister packages utilized according to the invention or to reduce the mechanic stress on the medication 2 when pushing in the dome 1, the cavity 1 can have an inwardly directed filler pin 28 or an inwardly directed spacer 28, which pushes through the cover foil 3 when pushing in the dome 1 so that the content of the cavity 1 can penetrate into the housing 33 of the device. This is shown in Fig. 8. Depending on the elasticity of the container foil 36 of the blister package, the original dome shape can be recovered after pushing in the dome 1, which is shown in Fig. 8, or the dome 1 can remain in pushed-in condition.

To also reduce the mechanic stress on the medication 2 when pushing in, the dome 1 can also be surrounded by a ring bulge formed in the container foil 36, as shown in Fig. 9. The ring bulge 29 effects a toughness of the container foil 36, in particular at the transition point 30 of the dome 1 into the ring bulge 29, which is in contact with the cover foil 3 and is pushed inward by a pressure exerted on the dome 1. In this way results a separation of the cover foil 3 in the transition area 30. It is basically also possible to configure the ring bulge 29 shown in Fig. 9 not as a complete ring bulge 29, but a partial part 31,

which is cut out as shown in Fig. 10. On this cutout 31, the cover foil 3 is not separated when opening the closed off cavity 1 but remains connected to the rest of the cover foil 3. /6

Reference Numerals List

1 cavity, dome

2 medication

3 cover foil

4 air inlet opening

5 mouthpiece-shaped outlet opening

6 fold corner

7 latch

8 snap lock

9 reinforced corner

10 groove

11 protective sleeve

12 opening in protective sleeve

13 rear wall of housing

14 mouthpiece

15 components as dispersion aid

16 reinforcement

17 simple winding

18 hollow body

19 rear attachment part

20 structure

21 side walls of rear attachment part

22/23 elements of the locking connection

24 holding edge

25 blister strip

26 check valve

27 fixing spacer

28 filler pin, spacer

29 ring bulge

30 transition point dome/ring bulge

31 recess in ring bulge

32 cavity in protective sleeve

33 housing

34 winding

35 front attachment part

36 container foil

37 groove in rear attachment part

Patent Claims

1. Device for administering medication in solid finely dispersed form in an air flow, which has an outwardly sealed housing (33) that forms an elongated inner chamber with a mouthpiece-shaped air outlet (5) arranged on a narrow side and an air inlet opening (4) arranged on the opposite side, characterized in that the housing (33) has, on its (their) main surface area(s), small cavities (1) for receiving the medication in a container foil

a) one or several folded and straightened simple windings (17) having hollow bodies (18) open to the narrow side, which contain the cavities (1) already filled with the medication (2) and closed off via the cover foil,

b) a front attachment part (35) with a mouthpiece-shaped air outlet (5), and

c) a rear attachment part (19) with a rear wall (13) having the air inlet opening (4), wherein both attachment parts (35, 19) are inserted and attached on the opposite-lying open narrow sides of the hollow body (18).

6. Device according to one of claims 1 to 3, characterized in that the housing (33) consists of structure(s) (20) open at its (their) main surfaces with a mouthpiece-shaped air outlet (5) and an air inlet opening (4) having one or several strips (25) which have cavities (1) already filled with medication and closed off via a cover foil (3) so that all open main surfaces are sealed to the outside.

7. Device according to one of claims 1 to 6, characterized in that the air inlet opening (4) is provided with a check valve (26), which opens when there is a small underpressure in the housing (33).

8. Device according to one of claims 1 to 7, characterized in that a hollow mouthpiece (14) is also provided, which can be

inserted into the mouthpiece-shaped outlet (5) of the housing (33).

9. Device according to one of claims 1 to 8, characterized in that components (15) are provided in the inner chamber of the mouthpiece-shaped air outlet (5), which improve the dispersion of the medication (2) in the air flow.

10. Device according to one of claims 1 to 9, characterized in that a protective sleeve (11) is also provided, which partially surrounds the housing (33).

- Blank Page -

Fig. 2a:

1. Section line A-B

Fig. 5a:

1. Section line A-B

Fig. 6c:

1. 2 parts

Nummer: DE 44 00 084 A1
Int. Cl.[6]: A 61 M 15/00
Offenlegungstag: 6. Juli 1995

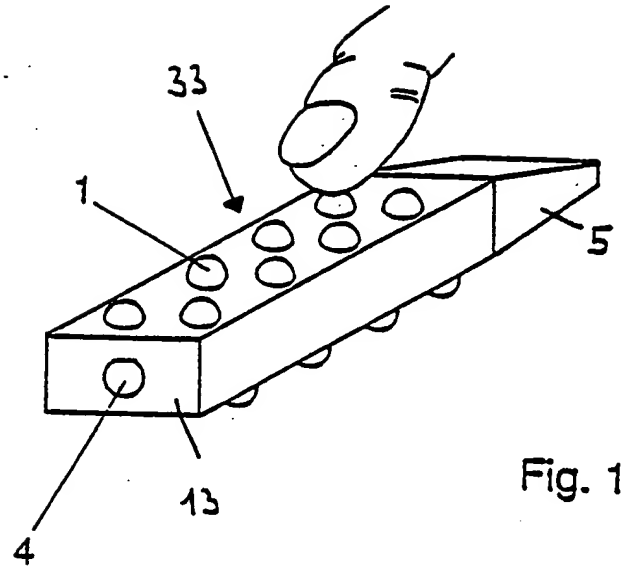


Fig. 1

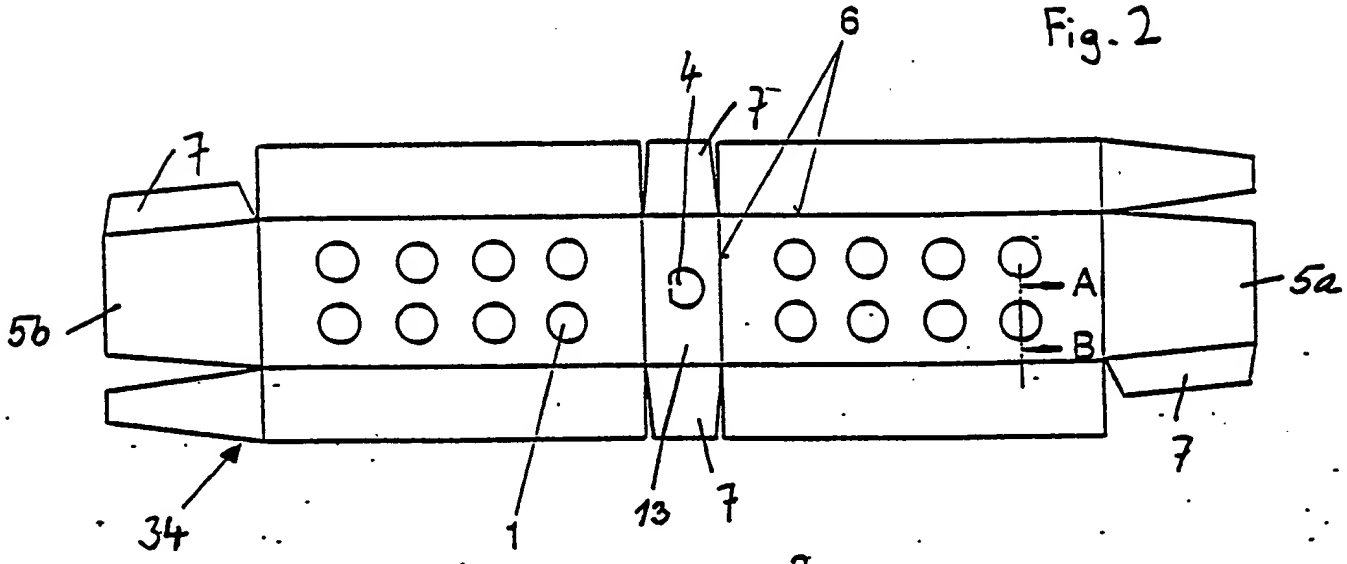


Fig. 2

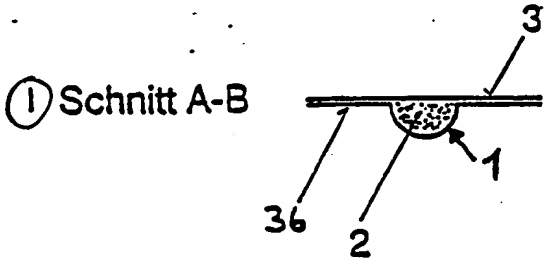
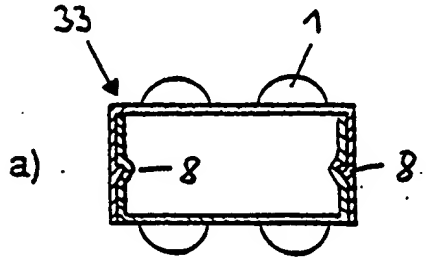
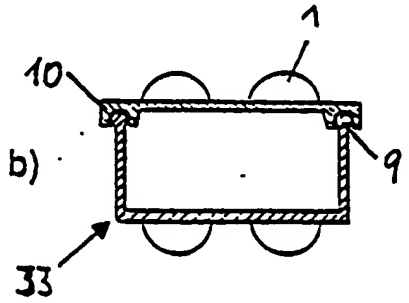


Fig. 2a

Fig. 3





Nummer: DE 44 00 084 A1
Int. Cl.[6]: A 61 M 15/00
Offenlegungstag: 6. Juli 1995

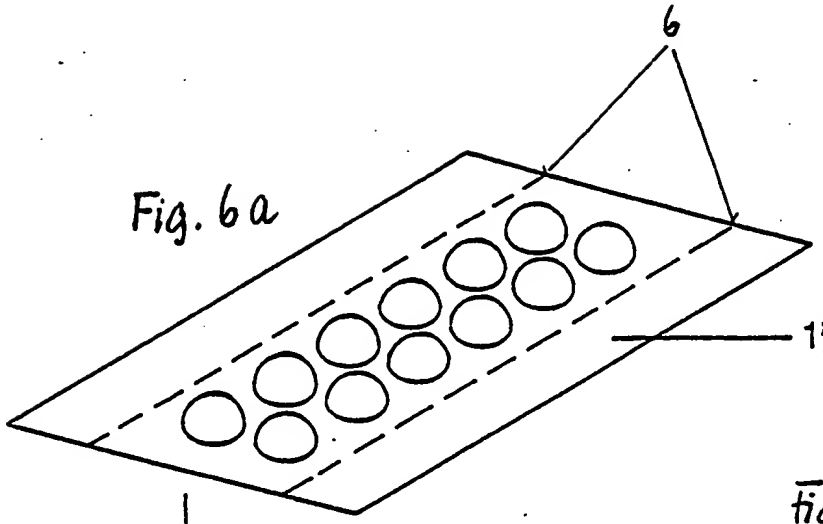


Fig. 6a

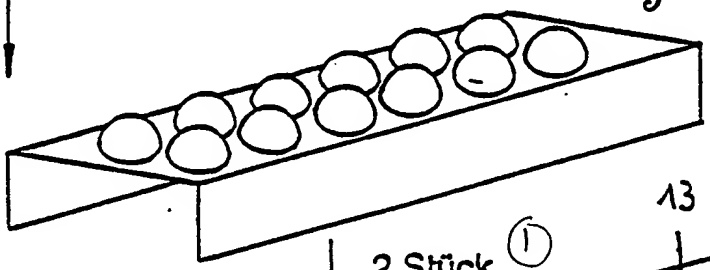


Fig. 6b

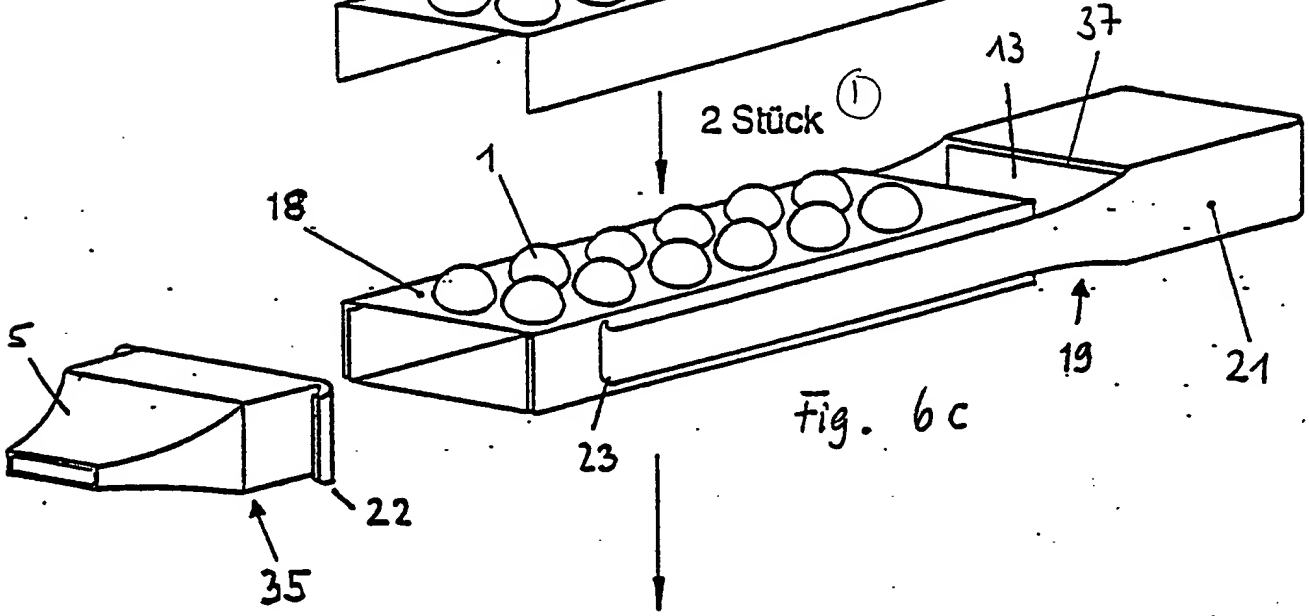


Fig. 6c

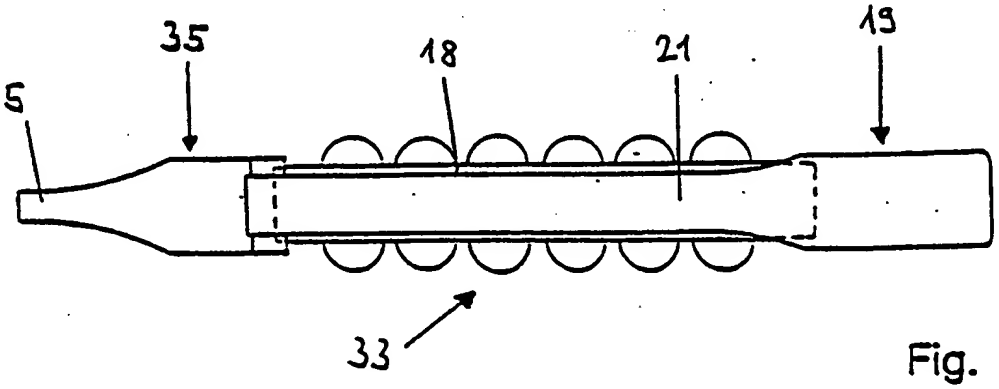


Fig. 6d

Nummer: DE 44 00 084 A1
Int. Cl.⁶: A 61 M 15/00
Offenlegungstag: 6. Juli 1995

Fig. 7a

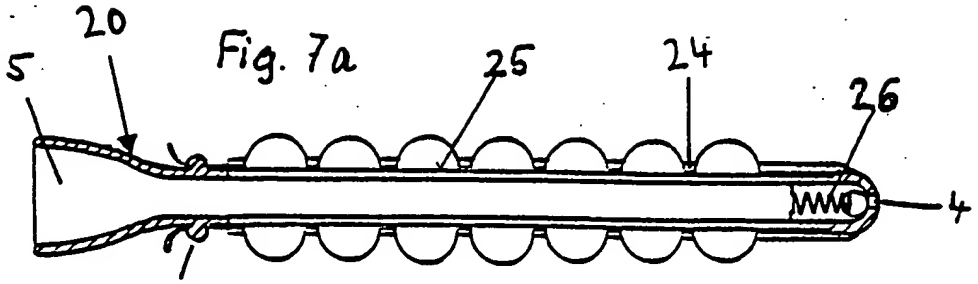


Fig. 7b

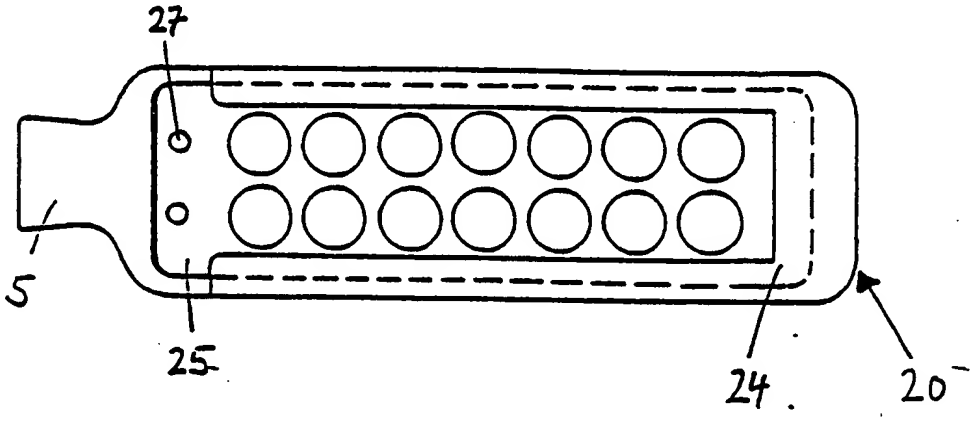


Fig. 8